IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES, *ex rel.*, DAVID W, STEBBINS,	)	
Plaintiff/Relator	)	
v.	)	**Civil No. 19-1524**
VASCULAR ACCESS CENTERS, LLC, VASCULAR ACCESS CENTER OF PITTSBURGH, PHILADELPHIA VASCULAR INSTITUTE, LLC, MAIN LINE VASCULAR INSTITUTE, LLC, VASCULAR ACCESS CENTER OF MAINLINE, LLC, PERIPHERAL VASCULAR INSTITUTE OF PHILADELPHIA, LLC, and JAMES F. MCGUCKIN,	)	
Defendants.	)	

Opinion

Relator David W. Stebbins commenced this *qui tam* action pursuant to the federal False Claims Act (FCA), 31 U.S.C. §§ 3729, *et seq.*, against Defendants Vascular Access Centers, LLC, Vascular Access Center of Pittsburgh, LLC, Philadelphia Vascular Institute, LLC, Main Line Vascular Institute, LLC, Vascular Access Center of Mainline, LLC, Peripheral Vascular Institute of Philadelphia, LLC and James F. McGuckin. The Relator alleges that Defendants submitted false claims for payment to the Medicare and Medicaid programs arising from procedures performed in their own, improperly licensed, facilities, instead of in properly state-licensed Ambulatory Surgical Facilities, in violation of the False Claims Act. 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B).

Presently before the Court is the Motion to Dismiss the Second Amended Complaint filed by Defendants Vascular Access Centers, LLC, Philadelphia Vascular Institute, LLC, Main Line Vascular Institute, LLC, Vascular Access Center of Mainline, LLC, Peripheral Vascular Institute of Philadelphia, LLC, and Dr. James F. McGuckin.[1] ECF No. 39. Relator has filed a Response in Opposition, to which the Defendants have filed a Reply. ECF No. 43 and 44. For the reasons explained below, Defendants' Motion to Dismiss will be denied in part, granted in part, and Relator will be given leave to file an amended complaint.

I. Background

A. Parties

Defendant James F. McGuckin, M.D. is a vascular and interventional radiologist, and is the owner, founder, principal, and a general partner of non-party Vascular Access Centers, L.P. (non-party VAC). Defendant Vascular Access Centers, LLC, is a general partner of non-party VAC. Dr. McGuckin, and/or non-party VAC, had a controlling ownership interest in the remaining Defendants: Philadelphia Vascular Institute, LLC, Main Line Vascular Institute, LLC, Vascular Access Center of Mainline, LLC, and Peripheral Vascular Institute of Philadelphia, LLC. Relator David W. Stebbins was employed by non-party VAC, from June 2006 through October 2018, as its Administrative Director.

B. Relevant Procedural History

The initial Complaint in this matter was filed on November 25, 2019. ECF No. 1. Two months later, Relator filed an Amended Complaint. ECF No. 2. Both complaints were filed under seal, and not served upon the Defendants, pursuant to the False Claims Act. 31 U.S.C. §

[1] The Court will refer to the six Defendants who have filed the present Motion to Dismiss as "Defendants." The docket does not reflect that Defendant Vascular Access Center of Pittsburgh, LLC (VAC-PGH) has been served, nor has VAC-PGH filed an Answer or a Motion to Dismiss.

3730(b)(2). Armed with "the complaint and written disclosure of substantially all material evidence and information the [relator] possesses," the government is given an initial 60-day period to investigate the relator's claims and to decide whether to intervene in the matter. *Id.* Pursuant to section 3730(b)(3), the government may seek an extension of time to investigate the allegations, while the Complaint continues to remain under seal. 31 U.S.C. § 3730(b)(3). When the government's investigation has concluded, the government shall inform the Court whether it will "(A) proceed with the action, in which case the action shall be conducted by the Government; or (B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action." 31 U.S.C. § 3730(b)(4). In either case, once the government makes its decision, the complaint is unsealed and the matter proceeds with the complaint being served upon the defendant.

Here, the government sought eight extensions of time to investigate Relator's allegations through May 8, 2023, at which time it informed the Court of its decision not to intervene in this action. ECF No. 26. The case was unsealed on May 9, 2023, and, pursuant to a stipulation with Defendants, Relator filed a Second Amended Complaint on September 1, 2023. ECF No. 33. Thereafter, Defendants filed their Motion to Dismiss, to which Relator filed his Response. ECF Nos. 39, 43. Defendants filed a Reply to Relator's Response, and later filed a Notice of Supplemental Authority. ECF Nos. 44, 45.

C. Allegations

The Second Amended Complaint asserts two causes of action. Count One alleges that Defendants knowingly presented, or caused to be presented, false claims for payment to the government. 31 U.S.C. § 3729(a)(1)(A). Count Two alleges that Defendants knowingly made, used, or caused to be made or used, false records and statements that were material to their false

claims. 31 U.S.C. § 3729(a)(1)(B). Relator specifically alleges that Defendants created and submitted Forms CMS-855I and CMS-1500, both of which included false representations and certifications and which also failed to disclose material information.

Relator alleges that the Defendants submitted false claims to Medicare and Medicaid, either directly or through their agents, employees, and contractors, for reimbursement for performing arteriograms and related intravascular ultrasound procedures. Performing an arteriogram, or a related procedure, requires the administration of anesthesia exceeding local or topical anesthesia. Administration of such anesthesia, such as general anesthesia, obtunds or dulls or deadens, the reflexes of patients. Relator alleges that Defendants performed the medical procedures in out-patient facilities that did not comply with Pennsylvania State Department of Health regulations regarding the administration of anesthesia. Specifically, pursuant to the "Definitions" section of the Pennsylvania Department of Health regulations, surgical procedures, that involve the administration of such anesthesia exceeding local or topical anesthesia, are to be provided only at acute care hospitals or Class B or Class C Ambulatory Surgical Facilities. 28 Pa. Code § 551.3 (**Definitions**). Relator claims that, because Defendants did not perform the medical procedures at an acute care hospital or at a Class B or Class C Ambulatory Surgical Facility, any claim, knowingly submitted for payment to Medicare or Medicaid, is a false claim.

Relator alleges that the falsity of the claims arises from the failure of Defendants to disclose to the government that the arteriograms and related medical procedures, for which they submitted claims, had been performed at facilities that were not properly licensed under Pennsylvania Department of Health regulations. The falsity of the claims also arises from the Defendants' failure to inform their patients that the procedures were going to be performed in violation of Pennsylvania Department of Health regulations. Relator alleges that Defendants'

failure to disclose such information to their patients, prior to performing the procedures, prevented the patients from being able to provide their fully informed consent. Finally, Relator alleges that, had the government known that the medical procedures for which Defendants sought payment had been performed at facilities that were not properly licensed, the government would not have paid Defendants' claims.

D. Motion to Dismiss

Defendants move to dismiss Relator's claims for failure to state averments of fraud with sufficient particularity, as required by Federal Rule of Civil Procedure 9(b). Defendants also move to dismiss Relator's claims for failure to state a False Claims Act claim upon which relief can be granted, pursuant to Federal Rule of Civil Procedure 12(b)(6). Finally, Defendants submit that Relator should not be given leave to amend his claims.

II. Standard of Review

A. Rule 12(b)(6)

When reviewing a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Eid v. Thompson*, 740 F.3d 118, 122 (3d Cir. 2014) (quoting *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The Supreme Court clarified that this plausibility standard should not be conflated with a higher probability standard. *Iqbal*, 556 U.S. at 678. "A claim has facial plausibility when the plaintiff pleads factual content that allows the

court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* 678 (citing *Twombly*, 550 U.S. at 556); *see also Thompson v. Real Estate Mortg. Network*, 748 F.3d 142, 147 (3d Cir. 2014). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. "Factual allegations of a complaint must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

B. Documents Permitted to be Considered

"Courts 'generally consider only the allegations contained in the complaint, exhibits attached to the complaint[,] and matters of public record' when evaluating whether dismissal under Rule 12(b)(6) [is] proper." *Levins v. Healthcare Revenue Recovery Grp. LLC*, 902 F.3d 274, 279 (3d Cir. 2018) (quoting *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993). A court, however, may "consider documents integral to or explicitly relied upon in the complaint or any undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." *In re Asbestos Prods. Liab.Litig. (No. VI)*, 822 F.3d 125, 133 n. 7 (3d Cir. 2016). "Otherwise, a plaintiff with a legally deficient claim could survive a motion to dismiss simply by failing to attach a dispositive document on which it relied." *Pension Benefit,* 998 F.2d at 1196. The United States Court of Appeals for the Third Circuit explains that consideration of such documents is proper because "'the primary problem raised by looking to documents outside the complaint—lack of notice to the plaintiff—is dissipated where the plaintiff has actual notice ... and has relied upon [those] documents in framing the complaint.'" *Levins*, 902 F.3d at 279-80 (quoting *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (internal quotation marks, alteration, and citation omitted).

Here, Defendants have attached as Exhibits two Local Coverage Determinations (LCD) issued by the Medicare Administrative Contractor in Pennsylvania, Novitas Solutions, Inc., identified as & (Ex. A, LCD35092 & Ex. D, LCD35084); a Medicare Physicians' Fee Schedule Guide (Ex. B); a Center for Medicare and Medicaid Services National Coverage Determination with respect to angioplasty procedures (Ex. C); and Wisconsin Physicians Service Insurance Corporation LCD L34761 (Ex. E). Each of these Exhibits is a publicly published undisputedly authentic document and each is a matter of public record. The Court takes judicial notice of such documents. Consideration of the Exhibits is proper insofar as they are directed at Plaintiff's Second Amended Complaint allegations.

C. Leave to Amend

When a court grants a motion to dismiss, the court "must permit a curative amendment unless such an amendment would be inequitable or futile." *Great W. Mining & Mineral Co. v. Fox Rothschild LLP,* 615 F.3d 159, 174 (3d Cir. 2010) (internal quotations omitted). Further, amendment is inequitable where there is "undue delay, bad faith, dilatory motive, [or] unfair prejudice." *Grayson v. Mayview State Hosp.*, 293 F.3d 103, 108 (3d Cir. 2002). Amendment is futile "where an amended complaint 'would fail to state a claim upon which relief could be granted.'" *M.U. v. Downingtown High Sch. E.*, 103 F. Supp. 3d 612, 631 (E.D. Pa. 2015) (quoting *Great W. Mining*, 615 F.3d at 175).

III. Discussion

As explained below, the Court finds that the Relator has sufficiently met the pleading requirements of Rule 9(b), but has failed to sufficiently plead all elements of a False Claims Act claim.

A. Rule 9(b)

"False Claims Act plaintiffs must [] plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b)." *Universal Health Servs., Inc. v. United States ex. Rel. Escobar*, 579 U.S. 176, 195 n. 6 (2016). Rule 9(b) provides as follows:

> **(b) Fraud or Mistake; Conditions of Mind.** In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.

Fed. R. Civ. Proc. 9(b). A Relator must plead "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014) (quoting *Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir.2009)). Defendants argue that the Second Amended Complaint fails to satisfy Rule 9(b)'s pleading requirement, specifically, by "lumping all Defendants" together. Defendants argue that Relator is required to inform each Defendant of the nature of his alleged participation in the fraud. *Tredennick v. Bone*, 323 Fed. App'x. 103, 105 (3d Cir. 2008) ("where multiple defendants are involved, the complaint should inform each defendant of the nature of his alleged participation in the fraud").

The purpose for the heightened pleading standard of Rule 9(b) is to provide defendants, who are alleged to have been involved in some sort of fraud, with fair notice of the claims being made against them so that they "can intelligently respond." *United States ex rel. Richards v. R & T Invs. LLC*, 29 F. Supp. 3d 553, 560 (W.D. Pa. 2014) (quoting *Illinois Nat. Ins. Co. v. Wyndham*

Worldwide Operations, Inc., 653 F.3d 225, 233 (3d Cir.2011)). In analyzing allegations under Rule 9(b), the Third Circuit Court of Appeals has adopted the "more nuanced reading of the heightened pleading requirement" applied by the First, Fifth, and Ninth Circuits. *Foglia*, 754 F.3d at 156. The Third Circuit adopted the "nuanced" approach as opposed to the more rigid approach employed by the Fourth, Sixth, Eighth, and Eleventh Circuits. The rigid approach requires "that a plaintiff must show 'representative samples' of the alleged fraudulent conduct, specifying the time, place, and content of the acts and the identity of the actors." *Id.* at 155. In *Foglia*, the Court noted that the Third Circuit "had never held that a plaintiff must identify a specific claim for payment at the pleading stage of the case to state a claim for relief." *Id.* (quoting *United States ex Rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 308 (3d Cir.2011)). Pursuant to the nuanced approach "it is sufficient for a plaintiff to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia*, 754 F.3d at 156.

The Court's review of the Second Amended Complaint shows that the allegations are sufficient to put Defendants on notice of the claims against each of them such that they can intelligently respond to Relator's allegations. Relator has specifically explained what the Defendants alleged wrongful conduct was, which leads to a strong inference that claims were actually submitted. *See* Second Am. Compl. at ¶¶ 51-62, 64-103[2]. Each Defendant is alleged to have participated in the same type of fraudulent conduct. Each Defendant is alleged to have failed to comply with Pennsylvania Department of Health regulations and failed to disclose their

[2] Among other allegations, the Second Amended Complaint alleges that physicians performed procedures in out-patient facilities, that such facilities were not in compliance with state regulations, that false claims were submitted as early as 2006 and continued to the date of the filing of the Second Amended Complaint, that Defendants submitted false claims deliberately, knowingly, and recklessly, that Defendants used identified CPT codes, and Relator alleges descriptions of the express false certifications, implied false certifications, and fraudulent inducement. Second Am. Compl. at ¶¶ 51-62, 64-103.

non-compliance when submitting claims to the government for payment. Each Defendant is also alleged to have failed to inform their patients of their non-compliance with the regulations. Such allegations are applicable to each Defendant. Each of the submitted claims is alleged to have been for a procedure performed in an improperly licensed facility on a date certain, which information would be in the possession of each Defendant. In summary, between 2006 and 2023, each Defendant is alleged to have submitted false claims, based upon having performed arteriograms and related medical procedures in an out-patient/office setting or other facility, without complying with state regulations. Each Defendant has access to their own records; and therefore, each would be able to determine what procedures were performed, where they were performed, and the date the procedures were performed. *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1989) (noting that Rule 9(b) is relaxed "when factual information is peculiarly within the defendant's knowledge or control"). Each Defendant also has access to their own Medicare and Medicaid records and claim submissions, from which they would be able to readily identify the claims at issue by matching claims to medical records. *Id.* Moreover, there are business and corporate relationships between and among all Defendants that permit each Defendant, either alone or together, to sort out each Defendants' particular role and to discern the participation and actions of each Defendant. Defendants' Motion to Dismiss, based on failure to comply with Rule 9(b), will be denied.

B. Failure to State a Claim

To state a claim under the False Claims Act, the relator must sufficiently allege four elements: falsity, causation, knowledge, and materiality. *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 94 (3d Cir. 2020) (*Druding I*). Defendants argue that the Second Amended Complaint fails to sufficiently plead falsity, materiality, and knowledge.

1. Falsity

An alleged false claim may be either *factually* false or *legally* false. *United States ex rel. Greenfield v. Medco Health Solutions, Inc.,* 880 F.3d 89, 94 (3d Cir. 2018). "A claim is factually false when the claimant misrepresents what goods or services . . . it provided to the Government." *Id.* A claim "is legally false when the claimant lies about its compliance with a statutory, regulatory, or contractual requirement." *Id.* "Legally false claims may be either express, where the claimant falsely certifies that it is in compliance with regulations, or implied, where the claimant 'seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment.'" *Druding v. Care Alternatives, Inc.*, 164 F. Supp. 3d 621, 627 (D.N.J. 2016) (quoting *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.,* 543 F.3d 1211, 1217 (10th Cir.2008)). A legally false claim may also be based on a fraudulent inducement theory, whereby a claimant enters into a fraudulently induced contract for government payment. For example, a claimant entering into a government contract may falsely certify that they will comply with rules and regulations when they submit claims for payment in the future.

Relator alleges that Defendants submitted legally false claims, by falsely certifying that Defendants have complied with governmental conditions required for payment. Namely, Relator alleges that Defendants failed to adhere to Pennsylvania Department of Health regulations for the arteriograms and related medical procedures at issue, and then falsely certified that they were in compliance with all regulations, by failing to disclose that they had violated said regulations.

a. Failure to allege that Defendants submitted *false* claims

Defendants argue that Relator is unable to sufficiently plead that Defendants failed to comply with a governmental condition required for payment; and therefore, Relator cannot

successfully plead falsity. Defendants point out that there is no explicit state or federal requirement that conditions payment of claims for arteriograms and related medical procedures upon those procedures being performed in an Ambulatory Surgical Center or hospital. Such factor is not alone dispositive, where *Escobar* concluded that the False Claims Act does not limit liability only to circumstances where the provider "fails to disclose the violation of a contractual, statutory, or regulatory provision that the Government *expressly* designated a condition of payment." *Escobar*, 579 U.S. at 190. However, Defendants also argue that, because the alleged breach of conditions, *i.e.*, compliance with state regulations and provision of full notice to patients, were not requirements for receipt of payment for arteriograms and related medical procedures performed in an out-patient/office setting, the submission of claims for payment of such services cannot have been false.

In support, Defendants aver that such medical procedures are explicitly permitted to be performed in an out-patient/office setting, and that the submission of claims and payment therefore was proper. *See* Ex. A., Novitas Solutions, Inc. "LCD L35902 – Diagnostic Abdominal Aortography and Renal Angiography" (angiograms are considered reasonable and necessary when performed in an out-patient/office setting); Ex. B, *CMS - Physician Fee Schedule Guide: How to Use the MPFS* [Medicare Physician Fee Schedule] *Look-Up Too*l (Mar. 2021) (indicating that CMS provides payment for procedures performed in a non-facility setting, such as an office). Both of these documents permit payment for the relevant medical procedures, when performed in an out-patient/office setting. Relator's allegation, that Defendants have submitted false claims for such procedures, fails the falsity test, because the government permits payment of claims, such as those submitted by Defendants, for medical procedures performed in an out-patient/office setting.

Relator relies on the assertion that Defendants are required to meet general, non-specific, compliance requirements under federal law. *See* CMS-8551 (when enrolling in the CMS program, the provider certifies that they would "abide by the Medicare laws, regulations and program instructions that apply to me"); Form CMS-1500 (when submitting a claim, the provider certifies that said claim "complies with all applicable Medicare and/or Medicaid laws, regulations and program instructions for payment"). Relator alleges that, when submitting claims for payment, each Defendant impliedly represented that it was in compliance with Pennsylvania Department of Health regulations. Relator's argument, however, paints far too broadly, if general Pennsylvania Department of Health regulations were to be applied as to all service providers. Implied wholesale knowledge and certification, as to all such regulations encompassed within the Pennsylvania Department of Health regulations, for purposes of False Claims Act claims is far too expansive. *See, e.g., Escobar*, 579 U.S. at 196 (addressing materiality, the Supreme Court stated: "if the Government required contractors to aver their compliance with the entire U.S. Code and Code of Federal Regulations, then under this view, failing to mention noncompliance with any of those requirements would always be material. The False Claims Act does not adopt such an extraordinarily expansive view of liability.")

Relator also argues that the Court should impose an implied requirement for federal payment, that such arteriograms must be performed in a facility that adheres to Pennsylvania Department of Health regulations regarding procedures to be performed in ambulatory surgical centers. However, the regulation at issue arises from Department of Health regulations. It is not a Medicare or Medicaid requirement. It is not a state licensure issue, as in the case of a license to practice medicine. There is a distinction between licensure, essential to the practice of medicine, and Department of Health regulations that designate a *facility* location for rendition of services.

As stated in a somewhat similar case, "Relator conflates facility licensure with individual provider licensure and regulations dealing with hospitals versus physician offices." *United States ex rel. Stebbins v. Maraposa Surgical Inc*., No. CV 1:22-10, 2024 WL 1299705, at *3 (W.D. Pa. Mar. 27, 2024). Defendants have pointed out that it is the Commonwealth of Pennsylvania that confers licenses upon physicians, not the Department of Health. The Department of Health regulations at issue apply to facilities (among other things). The Court concludes that Relator's allegations fail to sufficiently plead the element of falsity as to the allegation that Defendants submitted false claims. Relator will be permitted leave to amend.

b. Falsity Element of Informed Consent Allegations

Relator also claims that patients were thwarted from being able to provide fully informed consent, because Defendants failed to disclose to patients that the procedures were being performed in violation of Pennsylvania Department of Health regulations as to facilities for administration of anesthesia. Defendants argue that there is no federal payment condition precedent or any Pennsylvania state law or regulation that requires a physician to advise patients that the provider is, or is not, complying with Pennsylvania Department of Health regulations when performing a procedure in an out-patient/office setting. The "adequacy of the informed consent" obtained by Defendants and their doctors, "are claims more akin to a medical malpractice action and not an FCA action." *United States ex rel. Lord v. NAPA Mgmt. Servs. Corp.*, No. CV 3:13-2940, 2017 WL 5450757, at *10 (M.D. Pa. Nov. 14, 2017) (citing *Escobar*, 579 U.S. at 196 (a False Claims Act claim is based on "allegations of fraud, not medical malpractice"). Thus, Relator's False Claims Act allegation, concerning lack of informed consent, fail to state any claim under the Act.

c. Fraudulent Inducement

Finally, Relator alleges that Defendants violated the False Claims Act by fraudulently inducing the government to enroll Defendants as Medicare and Medicaid providers through false certifications of future legal compliance. Relator's argument relies on Defendants' alleged submission of forms CMS-1500 and CMS-855I. For the reasons stated above, such forms do not sufficiently support relator's claims that Defendants fraudulently induced the government to enter into the contract. Thus, the element of falsity has not been sufficiently plead for a False Claims Act claim premised upon a fraudulent inducement theory.

2. Materiality

"A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Escobar*, 579 U.S. at 181. "A materiality inquiry under the FCA is a holistic, totality-of-the-circumstances examination of whether the false statement has 'a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.'" *Farfield*, 5 F.4th at 342 (quoting 31 U.S.C. § 3729(b)(4) and citing *Escobar*, 579 U.S. at 193). The "materiality standard is 'demanding' and 'rigorous.'" *United States ex. Rel. Stebbins v. Jefferson Cardiology Association, P.C.*, No. 21-1803, slip op. at 2, Doc. 50 (W.D. Pa. July 11, 2023) (quoting *Escobar*, 579 U.S. at 181, 194). The requirement that the materiality element be demanding and rigorous is a reflection of the nature of the False Claims Act, which, the Supreme Court states, is not "an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar*, 579 U.S. at 194 (citation omitted).

The non-exhaustive list of factors for a court to consider when addressing the materiality element include, whether compliance with the regulation was an express payment condition, whether the noncompliance was minor or insubstantial or whether it goes to the very essence of the bargain, and evidence of the government's past action or inaction. *See United States v. Fillmore Cap. Partners, LLC*, No. CV 15-2134, 2024 WL 1051971, at *4 (E.D. Pa. Mar. 11, 2024) and *Farfield*, 5 F. 4th at 342, 346. The Supreme Court summarized the materiality inquiry as follows:

> In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Escobar, 579 U.S. at 194-95. Pursuant to *Escobar*, while any one factor may be relevant, it is unlikely that a single factor will be dispositive of the issue of materiality. *United States ex. Rel. Druding v. Care Alternatives*, 81 F.4th 361, 365 (3d Cir. 2023) (*Druding II*) (vacating grant of summary judgment "[b]ecause the District Court assigned dispositive weight to a single *Escobar* factor, government action, while overlooking the factors that could have weighed in favor of materiality—and despite an open dispute over the government's 'actual knowledge'" (quoting *Escobar*, 579 U.S. at 195)).

a. Whether compliance with the regulation was an express condition of payment

"Whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry." *Escobar*, 579 U.S. at 190. Specifically, a "misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." *Id.* at 194. Here, there is no express payment condition requiring compliance with the state regulations at issue for the medical procedures at issue. This conclusion is relevant, and weighs in favor of finding that materiality is lacking, but this conclusion is not dispositive of the materiality inquiry. *Id.* at 190.

b. Whether the noncompliance was minor or insubstantial

Next, the Court considers "whether the noncompliance is 'minor or insubstantial' or, instead, whether the noncompliance goes "to the very essence of the bargain.'" *Farfield*, 4 F.4th at 346 (quoting *Escobar*, 579 U.S. at 193 n. 5 (quoting *Junius Const. Co. v. Cohen*, 257 N.Y. 393, 400, 178 N.E. 672, 674 (1931)). Here, the government has paid Defendants' claims for the referenced medical procedures, at least since 2006. Defendants assert that the government paid the claims based, in part, on documentation suggesting that such claims are properly payable. *See* Novitas's LCD L35092 and the Medicare Physician Fee Schedule's, attached as Defendants' Exs. A & B, respectively). The Defendants thus argue that their alleged state regulatory noncompliance is minor or inconsequential, in part, because the relevant Medicare documentation, cited above, suggests that payment for office-based procedures is permitted; and thus, the government has, in fact, paid such claims for years. Consistent with this conclusion, this Court finds that Relator has failed to sufficiently allege that the government would not have reimbursed claims for arteriograms and related medical procedures had it been aware of Defendants' alleged violations of state regulations. Further, there are no factual allegations

indicating that the government "'consistently refuses to pay claims in the mine run of cases based on noncompliance with'" the state regulations at issue. *Farfield*, 5 F.4th at 346 (quoting *Escobar*, 579 U.S. at 195).

With respect to whether Defendants' noncompliance goes to the "very essence of the bargain," Relator cites several cases where the regulatory compliance at issue was clearly central to the government's condition of payment. These cases are distinguishable, in that, in each of them, the payment condition was obvious and central to the provision of medical services. In *Escobar*, on remand from the Supreme Court, the First Circuit Court of Appeals found, when addressing materiality, "that the government [expressly] conditioned MassHealth's payments on compliance with [state] licensing and professionalism regulations." *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 111 (1st Cir. 2016) (citing 130 Mass Code Reg. § 429.441(A)). In *Escobar*, the issue concerned the failure to ensure that patient care practitioners were properly licensed; a circumstance that is central to the provision of mental health care. In *United States ex rel. Alejandro v. Philadelphia Vision Center*, the District Court found that alleged false claims for eye exams, performed by a person who was *not* a Pennsylvania state licensed physician, concerned the "very essence of the bargain." No. 20-2027, 2022 U.S. Dist. LEXIS 18357, at *17 (E.D. Pa. Feb. 1, 2022). Again, central to the provision of eye exams is that the provider actually be licensed to provide such exams. Finally, in *United States ex rel. McIver v. Act for Health, Inc.*, the Court concluded "as a matter of law that [the health care provider] was required to comply with state licensing requirement as a condition of seeking reimbursement for home healthcare services." 536 F. Supp. 3d 839, 845 (D. Colo. 2021). In the instant case, compliance with state Department of Health regulations is not an express condition for receiving payment on claims and there is not any actual pre-payment

condition that mentions compliance with such state regulations, and compliance with the state Department of Health facility regulations at issue does not go to the very essence of the bargain. The Court concludes that the allegations of the complaint weigh in favor of finding that the noncompliance is 'minor or insubstantial' and does not go "to the very essence of the bargain." *Farfield*, 4 F.4th at 346. Therefore, the element of materiality is lacking.

c. Evidence of the Government's past action or inaction

The government has made payments to Defendants for claims that Relator claims were allegedly false for not complying with Pennsylvania Department of Health regulations. On the present allegations, it is unknown whether the government would have paid, or would pay, Defendants' claims, if Defendants disclosed that the medical procedures had been performed at a facility that did not comply with Pennsylvania Department of Health regulations. *Druding I*, 952 F.3d at 92. In *Druding II*, the Third Circuit Court remarked that "the government's inaction for fifteen years is evidence of immateriality," however, "whether that inaction is dispositive evidence of immateriality is another matter." *Druding II*, 81 F.4th at 374-75. Here, there are allegations of past payment, but there is no allegation regarding government action or inaction after the government became aware of the alleged violations and conducted its investigation.[3] This factor is therefore neutral.

d. Government's decision not to intervene in the action

The government's decision not to intervene in a False Claims Act case does not automatically support, or even strongly weigh against, a finding of no materiality under Third

[3] There are currently no allegations to show that the government had actual knowledge of the noncompliance, and if so, what subsequent action or inaction the government took based upon on such actual knowledge. Here, the government conducted an extensive investigation of the alleged violations from 2019 through 2023. There are no allegations in the Second Amended Complaint as to what the government has been doing with respect to claims filed since the government became aware of the Defendants' action, and since it investigated the Realtor's claims and opted not to intervene in this case.

Circuit case law. The Third Circuit Court of Appeals has stated that "intervention decisions are, at best, of minimal relevance." *Farfield*, 5 F.4th at 346 (noting that in "*Escobar*, the Government chose not to intervene, . . . , yet the Supreme Court did not mention this as a pertinent materiality factor"). Furthermore, the *Farfield* Court stated that it would undermine the purposes of the False Claims Act if the government's choice not to intervene were dispositive of the materiality element. *Id.*

While the government's decision not to intervene is not dispositive as to the materiality element, there are several cases demonstrating that the government's decision not to intervene, coupled with additional relevant government action or inaction, is strong evidence in favor of finding that the materiality element has not been met. *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017), *Polansky v. Exec. Health Resources*, Inc., 422 F. Supp. 3d 916, 938-39 (E.D. Pa. 2019), *United States ex rel. Cressman v. Solid Waste Servs., Inc.*, No. CV 13-5693, 2018 WL 1693349 (E.D. Pa. Apr. 6, 2018), and *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445 (7th Cir. 2016).

In *Petrato*, the Third Circuit relied upon evidence showing that the relator had disclosed to the government "material, non-public evidence" of the defendant's violations. *Petratos*, 855 F.3d at 490. Armed with such "actual knowledge" of defendant's violations, the government still chose to continue to pay defendants for approximately six or seven years prior to the Court's decision. *Id.* Government action, consisting of continued payments to defendants for several years, despite actual knowledge of violations, is understandably "very strong evidence" against a finding of materiality. *Escobar*, 579 U.S. at 195. In *Polansky,* the government did not merely decline to intervene, it had *moved to dismiss the complaint*. 422 F. Supp. 3d at 938–39. The

Polansky Court found that the government's action in filing a motion to dismiss was strong evidence that the materiality element had not been met. *Id.*

In *Cressman*, the summary judgment record before the Court showed that the government was aware of, and had investigated, defendant's alleged violations, and still continued to pay defendant for approximately four years. *Cressman*, No. CV 13-5693, 2018 WL 1693349, at *6. The *Cressman* Court explained that "[i]n the four years since learning of Plaintiff's allegations in this matter, including the regulatory violations asserted and relied upon by Plaintiff, the Department of Justice has not initiated any proceedings or taken any action against Defendant." *Id.* Similarly, the Seventh Circuit Court in *Sanford-Brown*, again on a motion for summary judgment, found a lack of materiality where the government's investigation revealed that no penalties were required, and termination of the contract with defendant was not warranted. 840 F.3d at 447.

Here, the government conducted an extensive and long-term investigation into Relator's allegations. The initial complaint was filed under seal on November 25, 2019. ECF No. 1. After eight extensions of time to investigate, the government ultimately decided not to intervene in this action on May 8, 2023. *See* ECF Nos. 7, 11, 14, 16, 18, 20, 22, 25, & 26. The government's decision not to intervene in this matter following its extensive and wide-ranging investigation, without more, while significant to the ultimate decision, cannot, at this stage, be dispositive of materiality. *Farfield*, 5 F.4th at 346. In addition, the Second Amended Complaint does not present detailed factual allegations to demonstrate that the government's decision not to intervene was accompanied by government action or inaction.

However, the Court concludes that the government's decision not to intervene. although not solely dispositive, does weigh against finding materiality for the following reasons. First, the

government sought eight extensions to continue its investigation, resulting in an investigation spanning approximately three and one-half years.[4] Second, the government has advised the Court of its extensive investigation efforts through its filings for extensions of time. That is, in each request for an extension, the government demonstrated that it was actively investigating the claims. Third, the government informed the Court, under seal, of the wide-ranging nature of the investigation, which included partnering with, among others, numerous federal and state agencies. Finally, after such an extensive, long-term, and wide-ranging investigation, the government's decision not to intervene in this matter "suggests to the Court that Defendants' noncompliance is immaterial." *Maraposa,* No. CV 1:22-10, 2024 WL 1299705, at *3.

e. Materiality Conclusion

In relation to the materiality element, applying a "totality-of-the-circumstances examination," *Farfield*, 5 F.4th at 342, and considering that the materiality standard is demanding and rigorous, *Escobar*, 579 U.S. at 194, the Court concludes that Relator has not sufficiently plead the materiality element.

3. Knowledge

Finally, Defendants argue that Relator has not sufficiently plead that Defendants *knowingly* violated a requirement material to the government's decision to pay a claim. Defendants argue that Relator has not plead specific facts to show that Defendants knew the government would not pay for the medical procedures they performed in an office setting. Fed. Rule Civ. Proc 9(b). The requirements at issue herein, in general, are Pennsylvania Department

[4] *Compare United States ex rel. Stebbins v. Maraposa Surgical, Inc.*, wherein the District Court stated that "the Department of Justice's decision not to intervene after two requests for extensions, . . . , suggests to the Court that Defendants' noncompliance is immaterial." No. CV 1:22-10, 2024 WL 1299705, at *3 (W.D. Pa. Mar. 27, 2024).

of Health regulations governing the provision of medical procedures in ambulatory surgical centers.

The Court agrees with Relator that, at the pleading stage, he has sufficiently plead knowledge. *See* Second Am. Compl. ¶¶ 2, 4, 56, 77-80. Rule 9(b) explicitly states that "knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. Proc. 9(b). In addition, the False Claims Act provides the following expansive definitions of knowledge:

> (1) the terms "knowing" and "knowingly" --
>
> > (A) mean that a person, with respect to information--
> > (i) has actual knowledge of the information;
> > (ii) acts in deliberate ignorance of the truth or falsity of the information; or
> > (iii) acts in reckless disregard of the truth or falsity of the information; and
> >
> > (B) require no proof of specific intent to defraud.

31 U.S.C.A. § 3729(b)(1). The allegations of the Second Amended Complaint, alleging that Defendants knowingly presented false claims, are sufficient at this stage under Rule 9(b) and the False Claims Act definitions of "knowing" and "knowingly." Accordingly, the Court concludes that, at this stage, Relator has sufficiently plead the element of knowledge. However, having found Relator's Second Amended Complaint fails to state a false claim sufficiently under the False Claims Act, the Relator's claims still fail.

IV. Conclusion

For the reasons stated above, Defendants' Motion to Dismiss is granted in part and denied in part.

The Motion will be denied as to Defendants' Motion to Dismiss Relator's claims for failure to comply with Federal Rule of Civil Procedure 9(b).

The Motion will be granted as to Defendants' Motion to Dismiss Relator's claims for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6). Specifically, the Court finds that Realtor has failed to sufficiently plead the elements of falsity and materiality of a False Claims Act claim. Realtor will be granted leave to amend his claims, consistent with this Opinion.

The Motion will also be granted to the extent that Relator's claims are premised either on a fraudulent inducement theory or on a theory that Defendants are required to obtain informed consent with respect to the Department of Health regulations at issue. Such theories will be dismissed with prejudice, as leave to amend would be futile.

An appropriate Order will be entered.

Marilyn J. Horan
United States District Judge

Dated: June 20, 2024